

Applicants: Kiran K. Chada et al.
Serial No.: 10/768,566
Filed : January 29, 2004
Page 2

REMARKS

Claims 1, 8, 9 and 17-19 as amended January 26, 2007 are pending in the subject application.

Applicants are pleased to note that all of the rejections under 35 U.S.C. § 112 have been withdrawn. Applicants appreciate the efficiency of the examination culminating in only one rejection remaining, namely the anticipation rejection under 35 U.S.C. § 102 based on the Xu et al. (U.S. Patent Application Publication No. 2003/0143610).

Applicants are filing this response to supplement the record with their reasons for differing with the March 5, 2007 Advisory Action. Applicants also maintain their prior remarks and incorporate them by reference herein.

Important for this analysis is the fact that Applicants' claims are directed to a *method* which achieves specific results by requiring specific steps. Xu et al. do not describe a method for achieving Applicants' claimed result, or a method requiring specific steps as required by Applicants. Indeed, Xu et al. do not disclose what the sFRP-5 peptide does, or for what purpose one skilled in the art could use the sFRP-5 peptide.

Xu et al. disclose that one should "modulate" sFRP-5 (Xu et al. call it SARP3). Precisely what "modulate" means is not defined; nor is the consequence a specific modulation defined. Thus, it impossible from Xu et al. to tell a) whether to increase or to decrease the sFRP-5 peptide, and b) what the consequence doing either would achieve.

Applicants' are the first to correlate that increasing sFRP-5 reduces adipose tissue. Applicants have thus claimed a method requiring increasing sFRP-5 to reduce adipose tissue.

Applicants: Kiran K. Chada et al.
Serial No.: 10/768,566
Filed : January 29, 2004
Page 3

These facts are not disputed on this record. Applying a genus species analysis to these facts, leads to the conclusion that the anticipation rejection of record is improper. Specifically, the disclosure of Xu et al. can be considered a generic disclosure and Applicants' claimed method a patentably distinct species. Applicants are aware of the guidance in M.P.E.P. § 2131.02 that even a generic disclosure can anticipate a species that can be "at once envisaged" from the genus. Under the facts of this case, however, one skilled in the art could not envisage from Xu et al. the correlation of two specific elements of Applicants' claims, namely that a) increasing sFRP-5 leads to b) a reduction of adipose tissue. Thus, Applicants' claimed specific method is patentably distinct over the genus of Xu et al.

The March 5, 2007 Advisory Action attempts to circumvent this necessary conclusion by relying on the doctrine of inherent anticipation. Applicants respectfully submit that the doctrine is ill suited for the fact pattern of this case.

Anticipation requires a finding that all elements of that claim are found in a single prior art reference. *Studiengesellschaft Kohle m.b.H. v. Dart Industries Inc.*, 726 F.2d 724, 727-28 (Fed. Cir. 1984). Any assertion that a claim element is inherently anticipated requires the record to "make clear that the missing descriptive matter is necessarily present in the thing described in the reference." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). "Inherency may not be established by probabilities or possibilities" but rather "must be necessarily present" in the single prior art reference. *Crown Operations Intl., Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1377 (Fed. Cir. 2002) (internal quotations omitted).

In contrast to the requirements of the inherent anticipation doctrine, the March 5, 2007 Advisory Action arbitrarily and in

Applicants: Kiran K. Chada et al.
Serial No.: 10/768,566
Filed : January 29, 2004
Page 4

hindsight selects one of the possible meanings of "modulate" in Xu et al. and proceeds to analyze the selected possibility as if such was actually disclosed and actually performed. This clearly contradicts the necessarily present requirement of the doctrine. See *Rapoport v. Dement*, 254 F.3d 1053, 1062-63 (Fed. Cir. 2001) (finding no anticipation because a treatment regime of three doses per day would not necessarily include administering a dose at the time of sleep, even though a dose could be administered at that time). Findings of inherency based on mere "probabilities or possibilities" are improper and have consistently been rejected by the courts. See *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (finding that a system claim was not anticipated by prior art that could be used to perform the same result with a slightly different structure).

Even if the arbitrary and hindsight selection of one possible meaning of "modulate" was proper, the teaching of Xu et al. would still amount to merely an instruction. Xu et al. clearly is not a disclosure of something actually occurring. Mere instruction to do something without actually doing it, however, is insufficient to anticipate a method claim under the doctrine. See *Mehl/Biophile Int'l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (holding that a prior art instruction manual did not anticipate a method claim requiring a substantially vertical hair orientation even though actual practice of the prior art would sometimes result in such an orientation).

Furthermore, the full and correct teaching of Xu et al. is capable of producing differing and inconsistent results. "Modulating" generically teaches both increasing and decreasing SFRP-5. Thus, Xu et al. teaches in part a method that would fail to reduce adipose tissue, thereby controverting the requirements of the inherent anticipation doctrine. *Glaxo Inc. v. Novopharm*

Applicants: Kiran K. Chada et al.
Serial No.: 10/768,566
Filed : January 29, 2004
Page 5

Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 988 (1995) (holding that prior art which did not always produce the claimed compound did not inherently disclose it).

Xu et al. cannot necessarily and always involve each and every element of the Applicants' claimed method. Therefore, the reliance on the doctrine of inherent anticipation is fundamentally flawed and improper to show that Xu et al. anticipate all of the elements of Applicants' claimed invention.

Finally, the Federal Circuit has held that a method claim is inherently anticipated only by the actual practice of the method, not by a mere possibility of a result of the method occurring if the method were actually performed. *Schering Corporation v. Geneva et al.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003). (The Federal Circuit found a claim to a *compound* inherently anticipated by a disclosure in a patent of administering to a patient a precursor which was necessarily converted in the patient to the compound. However, the Federal Circuit in *Schering* explicitly stated that the *method* of treatment claims were not inherently anticipated by such a disclosure.)

In summary, in addition to Applicants' prior arguments which are incorporated by reference herein, Applicants respectfully submit that it is improper to rely on the inherent anticipation doctrine to find in Xu et al. elements of Applicants' claims that are clearly absent in Xu et al.

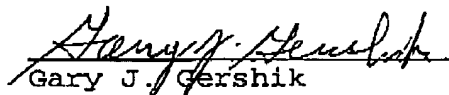
Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102 based on Xu et al.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is

Applicants: Kiran K. Chada et al.
Serial No.: 10/768,566
Filed : January 29, 2004
Page 6

hereby given to charge the amount of any such fee to Deposit
Account No. 03-3125.

Respectfully submitted,


Gary J. Gershik
Registration No. 39,992
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400